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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,324	06/22/2001	Juha Punnonen	0169.310US	7238

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EXAMINER

OUSPENSKI, ILIA I

ART UNIT PAPER NUMBER

1644

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/888,324	PUNNONEN ET AL.	
	Examiner	Art Unit	
	ILIA OUSPENSKI	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005 and 18 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 259-263, 265-302, 369 and 383-392 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 259-263, 265-269, 272-273, 276-277, 279-299, 302, and 383-392 is/are allowed.
- 6) ☒ Claim(s) 270, 271, 274, 275, 278, 300, 301 and 369 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>04/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment, filed 03/24/2005, is acknowledged.

2. The amendment filed 03/24/2005 is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see 68 Fed. Reg. 38611, Jun. 30, 2003). The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution.

The amendment is considered non-compliant because two claims have been assigned the same number 264.

However, in the interest of compact prosecution, misnumbered claims 264 (second occurrence) – 391 have been renumbered by the Examiner as claims 265 – 392, respectively.

3. Claims 264, 303 – 368, and 370 – 382, as renumbered, have been cancelled.

Claims 1 – 258 have been cancelled previously.

Claims 259, 261, 262, 266, 270, 274, 276, 278, 279, 282, 284 – 286, 288, 291 – 294, 298, and 299, as renumbered, have been amended.

Claims 383 – 392, as renumbered, have been added.

Claims 259 – 263, 265 – 302, 369, and 383 – 392, as renumbered, are pending and considered.

4. Applicant's IDS, filed 04/18/2005, is acknowledged, and has been considered.

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5. This Office Action will be in response to applicant's arguments, filed 03/24/2005.

The rejections of record can be found in the previous Office Action, mailed 09/24/2004.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

6. Submission of amended formal drawings:

Applicant's submission of amended formal drawings for Figures 8A, 8b, 9G, and 9H is acknowledged. Applicant states that the amendment corrects inadvertent typographical errors in formal drawings filed 11/26/2001, which were not present in original informal drawings filed 06/22/2001.

The drawings, as presently amended, appear to be consistent with original informal drawings filed 06/22/2001. The amendment to the drawings has been entered.

7. Sequence compliance:

Applicant's amendment to recite a SEQ ID NO in claim 292, as renumbered, appears to place the instant application in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

8. Objections to the disclosure:

Applicant's amendment obviates the objections of record against the Title, specification, and claim 264, as originally numbered.

However, the disclosure is objected to because of the following informalities: The description of Figure 8A – 8B on page 23 states that the sequences of “CD28BP-12 and CTLA-4BP 5x4-12c” are disclosed, which is not consistent with the labeling of the

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Figure panels. It appears that "CTLA-4BP-5x4-12c and CD28BP-15" has been intended. Appropriate correction or clarification is required.

9. Claim rejections under **35 USC 112, second paragraph**:

Applicant's amendments have obviated the rejections of record.

10. Claim rejection under **35 USC 112, first paragraph** – New Matter rejection:

(A) The rejection of record of claims 261 – 265, 270 – 271, 274, 277 – 278, 285 – 286, 293, 297, and 300 – 302, as renumbered, as it applies to the following ranges of amino acid residues of SEQ ID NO:66: 35 – 244, 35 – 245, 245 – 268, 269 – 303, 35 – 303, and 1 – 268, is withdrawn in view of Applicant's arguments.

(A) Applicant's amendment has obviated the rejection of record of claim 292.

(B) The rejection of record of claims 270 – 271, 275 – 275, 278, 300, and 301, as renumbered, as it applies to the following ranges of amino acid residues of SEQ ID NO:66: 246 – 272, 273 – 303, and 1 – 272, is maintained for the reasons of record, as explained in detail below.

Claims 270 – 271, 275 – 275, 278, 300, and 301, as renumbered, stand rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicants arguments have been fully considered, but were not found convincing as they apply to the following ranges of amino acid residues of SEQ ID NO:66: 246 – 272, 273 – 303, and 1 – 272.

Applicant argues that the specification shows “an alternative aspect of the transmembrane domain” of CD28BP-15 (SEQ ID NO:66), and points to Figure 8B of the originally filed informal drawings and the amended formal drawing replacement sheet 25/39 for written support for these limitations.

However, while it is acknowledged that the sequence LPFWHPVSGALVLTAVVLYCLACRH is shown by dashed underlining in the originally filed Figure 8B, and that this sequence corresponds to amino acids 246 – 272 of SEQ ID NO:66, this does not constitute adequate support under 35 USC 112, first paragraph. The Examiner was unable to find adequate support for Applicant’s assertion that this underlining represents “an alternative aspect of the transmembrane domain,” or that such alternative aspect of the transmembrane domain is part of Applicant’s invention, in the original disclosure.

Therefore, the rejection of record is maintained for the reasons of record, as it applies to the amended claims.

Applicant is required to cancel the New Matter in the response to this Office Action.

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

11. Claim rejection under 35 USC 112, first paragraph – Enablement:

(A) The rejection of record of claims 259 – 262, 266 – 279, 281 – 291, and 299270 – 271, 275 – 275, 278, 300, and 301, as renumbered, as not providing sufficient enabling description of polypeptide domains as they refer to sequences having a certain percent identity to SEQ ID NO:66, has been withdrawn in view of Applicant’s argument,

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and further in view of Figure 2 which appears to provide adequate delineation of domains of variant polypeptides.

(B) The rejection of record of claims 290 and 291, as renumbered, as not providing sufficient enabling description of polypeptides comprising modified amino acids has been withdrawn in view of Applicant's arguments.

(C) The rejection of record of claim 369, as renumbered, as not providing sufficient guidance and direction as to how to make and use a polypeptide which is specifically bound by a polyclonal antisera raised against the polypeptide of claim 259, is maintained for the reasons of record.

Given the absence of additional rebuttal to the outstanding rejection of record in applicant's amendment, the rejection is maintained for the reasons of record. The rejection of record, as set forth in the Office Action mailed 09/24/2004, is incorporated by reference herein as if reiterated in full. Applicant is invited to clarify whether Applicant has acquiesced to the rejection of record.

12. Claim rejection under **35 USC 102(b)**: the rejection of record of claims 259 – 262, 265 – 268, 272, 278, 282, 284 – 287, 289, and 298 – 299, as renumbered, has been withdrawn in view of Applicant's amendment and arguments.

Claim 369, as renumbered, stands rejected under **35 U.S.C. 102(b)** as being anticipated by Parsons et al. (Immunogenetics, 1999, vol. 49, pp. 231 – 234; see entire document).

Applicant's argument has been fully considered but was not found convincing.

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Applicant argues that if claim 259 is not anticipated by Parsons, no claim dependent upon claim 259 (including claim 369, as renumbered,) would be anticipated by this reference.

This is not found persuasive, because claim 369 encompasses polypeptides that are distinct from those of claim 259, as long as they are specifically bound by a polyclonal antiserum raised against the polypeptide of claim 259. Since a polypeptide taught by Parsons et al. shares extensive stretches of amino acid sequence identity with the polypeptide of SEQ ID NO:66, it would necessarily be specifically bound by a polyclonal antisera raised against a polypeptide of claim 259.

The rejection of record of claim 368 is maintained for the reasons of record.

13. Conclusion: claims 270 – 271, 274 – 275, 278, 300 – 301, and 369, as renumbered, stand rejected for the reasons of record.

Claims 259 – 263, 265 – 269, 272 – 273, 276 – 277, 279 – 299, 302, and 383 – 392, as renumbered, appear to be directed to allowable subject matter.

14. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

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May 26, 2005

Phillip Gambel
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5/27/05